

National Research Ethics Service

North West 9 Research Ethics Committee - Greater Manchester West

Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Telephone: 0161 237 2392
Facsimile: 0161 237 2383

09 December 2009

Professor Ian Bruce
Professor of Rheumatology
The University of Manchester
arc Epidemiology Unit,
Stopford Building
Oxford Road, Manchester
M13 9PL

Dear Professor Bruce

Full title of study: BILAG Biologics Prospective Cohort: The Use of Novel Biological Therapies in the Treatment of Systemic Lupus Erythematosus (SLE). (Lay title: Long-term Safety of New Biologic Treatments in the Management of SLE)

REC reference number: 09/H1014/64

Protocol number: 1.2

Thank you for your letter of 1 December 2009. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 11 November 2009. Please note these documents are for information only and have not been reviewed by the committee.

The REC has noted your alternative method of Consent and is happy with this proposed method.

I can confirm that the additional conditions have now been met.

Documents received

The documents received were as follows:

Document	Version	Date
Covering Letter		01 December 2009
Participant Information Sheet: Children	2	11 November 2009
Participant Information Sheet: Parents	2	11 November 2009
Participant Information Sheet: Adults	2	11 November 2009
Participant Consent Form: Parental Consent	2	11 November 2009
Participant Consent Form: Assent	2	11 November 2009
Participant Consent Form	2	11 November 2009
Questionnaire: Child Health Questionnaire (For children 5 years or older)	2	01 January 2004
Questionnaire: Childhood Health Assessment Questionnaire - Adolescent Version	2	01 January 2004

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Questionnaire: Childhood Health Assessment Questionnaire - for parents to complete	2	01 January 2004
--	---	-----------------

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

09/H1014/64**Please quote this number on all correspondence**

Yours sincerely



Miss Shehnaz Ishaq
Committee Co-ordinator

E-mail: Shehnaz.ishaq@northwest.nhs.uk

Copy to: Mr Mohammed Zubair – R&D Department University of Manchester
Dr Lynne Webster – R&D Department, Central Manchester and Manchester
Children's University Hospitals NHS Trust